Food Safety and Inspection Service
United States Department of Agriculture
Washington, D.C. 20250-3700

Export Library

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EXPORT REQUIREMENTS FOR THE EUROPEAN UNION

The United States and the European Union (EU) have reached a bilateral agreement on the export and import of animals and animal products. The conditions for the export of U.S. meat and poultry and meat and poultry products to the EU are part of this agreement, which become effective upon implementation of Council Decision 98/258/EC (referred to as the "Veterinary Equivalency Agreement.") These requirements become effective August 1, 1999.

The EU member countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

Finland and Sweden have additional requirements. See Section XIV for more information.

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I. ELIGIBLE/INELIGIBLE PRODUCTS

A. The products defined below are eligible for export to the European Union provided that the production systems used to produce them and all pertinent EU requirements are met.

1. "Meat" means all parts of domestic bovine animals (including bison), swine, sheep, goats, and solipeds which are suitable for human consumption. Note: For bison, FDA is the "competent authority" since the product is considered farmed game, however, since EU considers bison as fresh meat, FSIS conducts plant review and signs export certification. For further information on FDA regulations covering farmed game, contact Marilyn Balmer at (202) 205-4400.

2. "Fresh meat" means meat, including meat vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any treatment other than cold treatment to ensure preservation.

3. "Poultrymeat" means all parts fit for human consumption from domestic birds of the following species: domestic fowl, turkeys, guinea fowl, ducks and geese.

4. "Fresh poultrymeat" means poultrymeat, including meat which is vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any preservation process other than chilling or freezing.

5. "Offal" means fresh meat and fresh poultrymeat other than that of the carcass, even if it remains naturally connected to the carcass.

6. "Meat preparations" means meat (from carcasses, offals, poultrymeat, minced meat, wild game, or rabbit) which have had foodstuffs, seasonings or additives added to them; or which have undergone a treatment insufficient to modify the internal cellular structure of the meat and, thus, does not cause the characteristics of the fresh meat to disappear.

7. "Meat products" means products prepared from or with meat, including poultrymeat, which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat. The following are not meat products: meat which has undergone only cold treatment and products such as minced meat, meat in pieces of less than 100 grams, and meat preparations.

8. "Minced meat" means meat which has been minced into fragments or passed through a spiral-screw mincer.

9. "Other products of animal origin" are (1) meat extracts; (2) rendered animal fat: fat derived from rendering meat, including bones, and intended for human consumption; (3) greaves: the protein-containing residue of rendering, after partial separation of fat and water; (4) gelatin; (5) meat powder, powdered rind, slated or dried blood, salted or dried blood plasma; and (6) stomachs, bladders and intestines, cleaned, salted or dried, and/or heated.

10. "Farmed game" means land mammals or birds which are not considered as domestic and are not referred to in the definitions of meat or poultry meat, but which are farmed as domestic animals.

11. "Wild game" means wild land mammals which are hunted (including wild mammals living within an enclosed area under conditions of freedom similar to those enjoyed by wild game) and wild birds which are not covered by the EU farmed game meat directive.

B. Ineligible product - Fresh/frozen poultry and meat of farmed or wild game birds, including fresh/frozen meat of ratites, originating from birds raised or processed in the States of California, Nevada, and Arizona. These products are also ineligible from Dona Anna, Luna, and Otero counties in New Mexico, and El Paso and Hudspeth counties in

Texas.*

II. FACILITY, EQUIPMENT, AND PROCEDURAL REQUIREMENTS

Meat and poultry establishments must be under FSIS inspection in order to be eligible for export to the EU. The following requirements are in addition to FSIS domestic requirements or, if a domestic requirement, an area of special emphasis in the US/EU agreement.

A. Packaging material

l. Packaging material shall be kept in separate rooms that are used exclusively for this purpose and free of dust and vermin.

2. Packaging material shall not be stored on the floor.

3. Waxed assembled boxes shall not be nested, unless a liner will be added prior to filling.

4. Assembled boxes with liners shall not be nested.

5. Boxes shall not be handled by personnel who are handling exposed product.

6. Boxes shall be assembled in a sanitary manner, either in a separate room or, if in the processing room, never within 3 meters of exposed product.

B. Facility requirements for walls and floor junctions

1. Walls shall be smooth, durable, impermeable, and of a color which permits detection of insanitary conditions.

2. Walls shall have washable surfaces.

3. Walls and floor junctions shall be constructed and maintained so as to assure that surfaces are clean and free of contamination. Establishments that do not use cove molding to provide a smooth transition from floor to wall to facilitate cleaning must provide an equivalent alternative means, such as sealing of cracks between walls and floors, to maintain sanitary conditions.

C. Pallets in exposed product areas - The use of wooden pallets in areas where there is exposed product shall be phased out. Until such time:

1. No wooden pallets shall be used within 3 meters of exposed product.

2. All pallets shall be clean and structurally sound.

3. Wooden pallets shall be covered with a sanitary plastic slip sheet covering the entire top of the pallet.

4. Those establishments which are already using plastic pallets shall continue to do so.

5. When wooden pallets are used in coolers or freezers, all product present shall be hygienically packaged to prevent contact of product with wood.

D. Separation of lavatories and work areas

Toilet rooms shall be properly ventilated and shall be separated from exposed product rooms by either a vestibule or a dressing room.

E. Dry storage of non-food material

Detergents, disinfectants and similar substances shall be stored separately from food and from wrapping and packaging material.

F. Waste water

All establishments shall have an efficient drainage and plumbing system, and all drains and gutters shall be properly installed with traps and vents approved by FSIS, in accordance with 9 CFR 308.3(c) and 9 CFR 381.49(a),(c).

G. Separate storage of edible and inedible products

Condemned and other inedible meat and offal shall be removed in a hygienic manner, and as quickly as possible, from rooms containing edible material.

H. Separate storage of packaged and unpackaged products

Unpackaged exposed meat may not be stored in chilling or freezer rooms containing packaged meat.

I. Structural wood

Wooden structures shall be in good condition, impermeable, smooth, durable, rot-proof and sealed with a waterproof coating.

J. Use of suspended showers, sprays and hoses

1. Such devices shall not be used as a substitute for handwashing facilities.

2. Meat shall not be contaminated by splashing.

K. Sterilization of utensils and implements

Establishments shall provide sterilization equipment (batch or local sterilizers) to clean utensils as often as necessary. Implements such as knives or hooks which come into contact with meat shall be cleaned and sterilized frequently, and whenever they have been in contact with contaminated material or surfaces such as the external surfaces of hides. Sterilization shall be done with >180° F (82° C) water.

L. Accommodation for sick and suspect animals

1. Wood shall not be used for pens for sick and suspect animals.

2. Sick and suspect animals shall not be allowed to come into contact with animals intended for slaughter for export to the EU.

3. Pens for sick and suspect animals shall be sited and constructed to preclude contact with animals intended for slaughter for export to the EU, and effluent from such pens shall not flow into adjoining pens or passageways.

M. Stunning

The injection of air during stunning is prohibited.

N. Opening of stomachs and intestines

There must be a separate room for emptying and cleaning stomachs and intestines, unless the processing is done by closed-circuit mechanical equipment which avoids contamination and eliminates odors.

O. Batch condemnation

If carcasses, offals and blood are not correlated at the final postmortem inspection point, a batch system shall be operated in such a way that the Inspector in Charge (IIC) can demonstrate that if a carcass is condemned its offal and blood shall also be condemned.

P. Casings

Casing destined to the EU must be processed in EU approved establishments that are operating under FSIS' inspection program, as well as comply with the following additional EU requirements:

1. Medical certification for product handlers as outlined in Section III of these requirements.

2. Water testing requirements as outlined in Section IV of these requirements.

3. Hand wash basins in processing rooms and lavatories must not be hand-operated.

4. Walls must be light colored, with washable coating, up to a height of 2 meters.

5. The use of wood is not allowed. However, wooden pallets may be brought into processing rooms solely for the transport of packaged casings.

III. EMPLOYEE MEDICAL CERTIFICATION

A. Prior to employment, new employees shall be examined and certified by a medical doctor or by a person with

appropriate medical training (e.g. a physician's assistant or a registered nurse) working under the supervision of a medical doctor. The EU does not mandate specific disease testing (e.g. hepatitis, tuberculosis, etc.) Specific disease testing is left up to the professional judgment of the medical professional that is signing the certification. Acceptable terminology for the medical certification would be: "Having examined (employee name) on (date), it is my opinion that he/she is not suffering from any condition that would render him/her unfit to work with meat or meat products."

1. Establishments shall have in place an appropriate program to continuously monitor employee health by one of the health professionals described in A.

2. All cases of suspected diseases shall be referred to a medical doctor for diagnosis.

3. Establishments shall keep records of medical examinations and shall make those records available to auditors upon request.

4. The medical certification requirement only applies to those employees who handle exposed product.

IV. WATER TESTING

Pending EU review of the U.S. water standards, water testing in slaughter and processing establishments shall be carried out as follows:

A. The initial water testing requirements are as follows:

Test	Sample size	Temp.	Maximum conc.
Total coliforms	100 ml	37° C	Membrane filter - 0 or MPN < 1
Fecal coliforms	100 ml	37° C	Membrane filter - 0 or MPN < 1
Fecal strep	100 ml	37° C	Membrane filter - 0 or MPN < 1
Sulphite-reducing Clostridia	20 ml	37° C	MPN < 1
Total Plate Count	1 ml	37° C	Guide level - 10
	1 ml	22° C	Guide level - 100

B. Subsequent water testing

1. Frequency:

a. Annually, if municipal source of water and no intermediate storage in the plant.

b. Monthly, if private source of water or intermediate storage is used

2. Two examinations are required:

a. Total plate count at 37° C and 22° C incubated for a minimum of 72 hours,

b. and total coliform at 37° C incubated for a minimum of 48 hours.

3. Sampling

a. Samples must be taken from randomly selected water taps within establishments.

b. A diagram of tap locations and log of which taps have been sampled should also be maintained.

4. Test results

If test results are not within the required parameters, immediate retesting must be done. The retesting requirements are the same as the initial testing requirements.

5. Chlorination testing

A daily chlorination test is required if the private water supply or plant water supply is chlorinated for potability

C. The EU water testing requirements do not apply to cold storage facilities where only packaged meat is handled. However, these facilities must comply with FSIS the water potability requirement.

V. ANTEMORTEM INSPECTION

Antemortem inspection will be performed by FSIS in accordance with 9 CFR 309 and according to FSIS procedures.

A. Cattle

1. Cattle under 30 months of age:

a. Inspection by an FSIS veterinarian or;

b. Antemortem inspection may be performed by an official FSIS inspector with appropriate training, knowledge, skills and abilities provided that:

(1) the animals originate from a premise where an APHIS accredited veterinarian is present on an ongoing basis, and

(2) a letter from the premise confirming such presence must be on file at the

plant.

2. Cattle over 30 months of age must be inspected by an FSIS veterinarian.

B. Swine

1. Swine under 1 year of age will be inspected by FSIS in accordance with FSIS procedures.

2. Swine over 1 year of age must be inspected by an FSIS veterinarian.

C. All animals demonstrating abnormal signs shall be diagnosed and disposed of by an FSIS veterinarian.

VI. PIG HEART INCISION

A. For market hogs (animals up to 1 year old), the following number of swine hearts from inspected and passed carcasses at each approved slaughter establishment must be incised and their interior surfaces inspected by the IIC:

1. Six (6) hearts per establishment per week (or a rate to yield 300 hearts/establishment/year) must be incised and their interior inspected. IICs should randomly select one time per week to conduct the inspection. During this time, 6 hearts should be randomly selected. Each of the hearts should be laid open for examination of the endocardium in all chambers and associated valves. Although the best location for conducting the inspection may vary from plant to plant, an appropriate location may be in the offal packing area near or at the heart washer exit.

2. Gross pathological lesions, including lesions of endocarditis, should be described on the EU Pork Heart Weekly Data Sheet. Negative findings should also be recorded on a weekly basis. The Data Sheets should be maintained on file in the inspection office. Plant management should submit copies of the Data Sheets to the Export Staff of the Officer of International Affairs, Washington, DC, Phone (202) 720-6400, Fax (202) 720-7990 on a quarterly basis.

B. For sows and boars (animals over 1 year of age) from which meat or offal destined for the EU is produced, each heart must be incised and its interior surfaces inspected by FSIS personnel. Procedures have not been developed to conduct this inspection. Therefore, meat and offal from these animals cannot be exported to the EU at this time.

VII. TRICHINAE

A. Pork meat and horsemeat shall be subjected to cold treatment according to 9 CFR 318.10

OR

B. each pork or horse carcass shall be tested for trichinae at the time of slaughter. Testing requires the following elements:

1. The laboratory performing the tests must participate in the USDA, Agricultural Marketing Service (AMS) Trichinae Analyst and Laboratory Certification Program.

For further information about this program, contact AMS:

Isaac Sterling (202) 720-5898

Chemist, USDA, AMS, STD, TSB

P.O. Box 96456, Room 3517-South

14th & Independence Avenue, S.W.

Washington, DC 20090-6456

2. Each establishment must have a written program and procedures in place that assures that only product from carcasses that have tested negative for trichinae are certified for export as such. This program must include sampling procedures, testing procedures according to the AMS program, as well as non-cominglement procedures throughout slaughter, fabrication, processing, and packaing.

3. The IIC will review the establishment's written control program to determine if it is adequate to maintain controls. FSIS inspection personnel will perform random checks of these procedures in operation as well as checks of the records maintained by plant management. If problems are observed in the program during the checks, the Export staff at the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 should be notified through supervisory channels. Meat produced during this time should not be certified for export to the EU.

VIII. ANTIMICROBIAL TREATMENTS

Antimicrobial treatments (for example, hyperchlorination, TSP, organic acids, etc) are not allowed for treatment of red meat or poultry carcasses, parts or viscera. Only the application of water or steam is permitted.

IX. POULTRY CHILLING:

A. Immersion chilling of carcasses must meet the following requirements:

1. Carcasses must move through the chiller against a counterflow of water.

2. Recirculation of chiller water is not allowed.

3. The temperature of the water in the chiller must not exceed 61° F at the carcass entry and 4 0° F at the carcass exit.

4. The following amounts of water are required per bird:

Bird size	Inside/outside washer	chiller
<5.5 lb	0.40 gal	0.65 gal
5.5 to 11 lb.	0.65 gal.	1.00 gal.
> 11 lb.	0.90 gal.	1.50 gal.

5. Water consumption during carcass washing and immersion chilling, temperature of the water at the entrance and exit points of the chiller, and the number of carcasses in each weight range must be measured and recorded.

B. Alternative chilling systems to IX.A.1-5. may be used if they demonstrate a decreased microbial load for: aerobic plate counts; enterobacteriaceae; and E. coli before and after chilling. FSIS will validate and assess the data before the establishment is proposed for listing for export to the EU. This validation and assessment shall be carried out without the use of antimicrobial treatment, throughout a full day's production.

During the course of the day, plant management should select 30 or more carcasses prior to entry into the chiller and the same number of carcasses at the exit of the chiller. Samples should be taken randomly throughout a day's production. Whole bird rinses should be used for sample collection. Analysis of samples should be done using an AOAC International approved method. Plant management should submit a report of the assessment and results to the Export Staff of the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990.

This assessment shall be carried out each time any changes are made to a plant's chilling system. Records shall be kept of the validation and assessments, and shall be available to the EU.

C. Poultry temperature requirements

1. Poultry shall be chilled to an internal temperature of 40° F in the shortest time possible after slaughter.

a. In the case of small birds (up to 6 pounds), the internal temperature of 40° F shall be achieved by the end of the immersion chilling process.

b. Where crushed ice is used to chill large birds (over 6 pounds) after immersion chilling, such use must not result in cross contamination of the product. The use of boxes with leak holes for this purpose is not acceptable. Tanks or vats such as those specified in 9 CFR 381.66 (c) (4) (ii) should be used.

2. When further processing (cutting) occurs after poultry has been chilled to 40° F, the internal temperature may exceed 40°F for a maximum of one hour, but may not exceed 50° F.

D. Crushed ice

1. The use of crushed ice must not result in cross contamination of the product. When crushed ice is used for further transport or storage, stacking of boxes with leak-holes or other practices which could result in

cross contamination shall be prohibited.

X. RESIDUE TESTING

EFFECTIVE February 2002, all samples collected under the EU Additional Residue Testing Program will be forwarded to Maxxam Analytics, Inc. in Canada for screening.

A. All slaughter establishments approved for export of meat and/or offals to the EU are required to participate in the EU Additional Residue Testing Program.

B. The cost of analysis is the responsibility of the establishment management. Questions concerning analytical costs may be addressed directly to the laboratories participating in the program.

Any laboratory conducting analytical residue chemistry for the EU additional residue testing program must have the capability to detect the compounds included in the tables below at the level of detection specified by the EU. The specified parameters to qualify analysts under this program can be obtained by contacting FSIS, International Policy Staff at (202) 720-6400. FSIS provides technical assistance, analytical and monitoring components to assess and oversee the analytical performance of each laboratory.

C. The species, target compounds, and numbers of samples to be collected are listed in the table below. The targeted number of samples for each species is based on the total number of head slaughtered by all EU approved establishments of the species from the previous year. The number of samples to be collected at each establishment will be predicated by the number and the volume of EU destined product slaughtered.

Table 1: EU Residue Sampling Frequency for Red Meat

Table 2: Draft EU Residue Sampling Frequency for Poultry

D. Each EU approved slaughter establishment must make arrangements with the EU Export Group, an industry organization that has contracted the services of Maxxam Analytics Inc., in order for the laboratory to perform analyses included in this testing program. Contact the Export Staff of the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990, for assistance.

E. Sample request forms (FSIS form 10,210-3) will be preprinted and sent directly to the FSIS Inspector-in-charge (IIC) at the EU approved slaughter establishment periodically throughout the year. These forms will designate the date samples are to be collected (within 30 days of the specified date), tissue to be collected, the code for the residue which will be analyzed, and the laboratory designated to perform the analysis.

F. The IIC is responsible for collecting, securing and freezing the samples. These samples will be sent to the designated lab via overnight express mail in containers provided by the slaughter establishment, at the expense of the slaughter establishment. Sample selection and shipment of the samples cannot be delegated to plant management. When samples are sent out of the United States for analyses, plant management must use a company that will deliver perishable products in a timely fashion and must provide International airbills. To avoid unnecessary delays, include all appropriate

documents for entry into the country where the samples are destined.

G. Any questions related to sample collection under the EU Additional Residue Testing Program should be directed to the Export Staff, Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990.

XI. NON-HORMONE TREATED CATTLE (NHTC) PROGRAM: BEEF AND VEAL (formerly referred to as the Hormone Free Cattle (HFC) programs)

All bovine meat exported to the European Union must originate from animals that have never been treated with hormonal growth promotants. In order for FSIS to provide export certification for this product, there must be assurances that there are effective controls in all phases of production, from birth to slaughter, and subsequent processing and final packaging activities. An NHTC program is not required for bison.

Producer affidavits supplied by the grower, producer, and feeder will provide assurances that each individual animal in the entire lot of cattle presented for slaughter has never been fed or treated with hormonal growth promotants. Each phase of the production of these animals will maintain a written control program that describes the procedures for maintaining identity of and segregating non-hormone treated cattle, as well as the controls that are in place to prevent the administration of restricted compounds to the animals. The documented system will be audited by the Agricultural Marketing Service (AMS), Livestock and Seed Program or by an AMS-accredited independent third party system. Contact the AMS Meat Grading and Certification Branch at (202) 720-1113 for additional information regarding this program. AMS Website.

Guidelines have been developed for the industry by FSIS, which provide the system requirements and expected components of the program (FSIS' Program for Certifying Non-hormone Treated Beef to the European Union.) AMS has developed instructions providing the general policies and procedures for providing service under the NHTC Program. See documents prepared by AMS, Meat Grading and Certification Branch (MGCB): "MGC Instruction 708," "Live Animal Production Guidelines, " and "Slaughter Fabrication Guidelines" at the NHTC Web Page provided by AMS. Contact FSIS Export Staff at theOffice of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990, if necessary, for a copy of these documents.

A. Beef and veal production

1. Each phase of the production of these cattle, from birth through delivery at the slaughter establishment, must receive third party verification prior to FSIS certifying NHTC to the EU.

2. A copy of a signed producer affidavit certifying that the animals have never been treated with hormonal growth promotants must accompany each lot of cattle presented to the slaughter establishment. (Example of Producer Affidavit) This affidavit can be transmitted electronically or by facsimile, but must be available when the shipment of cattle arrives at the establishment.

a. All cattle must be slaughtered and processed in a federally inspected establishment approved for production of products destined for the EU.

b. Each establishment must have a written program and procedures in place that will assure the production and shipment of product derived from animals that have never been

administered hormonal growth promotants. AMS (or an AMS accredited independent third party) will review the program documentation for receiving cattle into the beef slaughter operations to ensure adequacy and continuity of animal identification procedures from the producer to the slaughter facility. Contact AMS, LSP for additional information regarding this program and to schedule the initial compliance review, which will be coordinated with the FSIS Export Coordination Staff, TSC. FSIS in-plant inspection personnel will ensure adequacy of the controls through the slaughter and processing establishment and will maintain operational oversight in the establishment.

B. Dairy/breeding cow product production

Pending further discussion with the EU, cow meat and cow offal will not be eligible for export to the EU unless it is produced according to the NHTC program guidelines referenced above.

C. In-process Controls

Each establishment involved in the production of NHTC beef must maintain documentation in accordance with an approved written control program and follow procedures that will assure the production and shipment of product derived from non-hormone treated cattle. Mandatory in-plant controls include:

1. Plant management must maintain documents to record the number of animals presented for slaughter and the number of animals slaughtered under EU mode of production.

2. Product destined for the EU must be appropriately identified and segregated throughout production according to the establishment's written control program.

3. Slaughter establishments must perform 100% palpation of the ears for hormone implants of all cattle or veal to be slaughtered under the NHTC program. This is to be done with the oversight of the FSIS/IIC.

4. Slaughter establishments must issue an affidavit confirming the non-hormone treated status of meat shipped to cutting plants without an EU Health Mark applied in a tamper evident fashion (Example of Transfer Affidavit). Adequate records supporting control of product transferred to separate processing facilities and cold storage warehouses must be maintained by plant management.

D. FSIS Inspector-in-Charge Responsibilities (IIC Procedures)

The IIC will verify that the establishment's written control program is adequate to maintain product and identification controls throughout the slaughter, fabrication, processing, packaging process, to the point that the EU Health Mark is applied in a tamper evident fashion. FSIS inspection personnel will perform random checks of these procedures in operation throughout the EU production, as well as checks of the records maintained by plant management. In addition, FSIS will check company records, when necessary, to verify proper transfer for subsequent storage prior to certification of the product to the EU. Compliance oversight by FSIS includes:

1. Familiarity with the establishment's written control program.

2. Verification that the NHTC lot comes from an AMS approved premise. The affidavit will be reviewed to confirm that it complies with the parameters outlined in the establishment's written control program,

including animal identification and authorized affidavit signer controls. The affidavit can be transmitted electronically or by facsimile but must be available for the verification check at the time the shipment of cattle arrives at the slaughter establishment. Cattle arriving at the slaughter establishment without adequate identification or certification (producer affidavit) will not be permitted to be slaughtered for the EU until the deficiency is corrected according to the company's control procedures.

3. Performing additional random procedures to determine compliance with the program. Procedures will include all aspects from receiving through shipping and may include observation, review of records, or both. All records from an entire lot of product will be reviewed on a periodic basis. Reviewed records will be signed and dated.

4. If there is noncompliance with EU requirements or with the establishment's control program, the IIC will notify management and request correction of the deficiency. If a deficiency is not corrected, the IIC will withhold the EU health mark label (or brand). The labels (or brand) will be returned to the IIC and secured until correction is made. The IIC will document the noncompliance.

5. If repeated deficiencies occur, or a non-compliance is not corrected in a reasonable time period, the Export staff at the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 shall be notified through supervisory channels.

E. Special Residue Testing Program for the NHTC Program

Effective immediately, the Special Residue Testing Program for the NHTC has been suspended. All analytical testing for melengestrol acetate (MGA), zeranol, and trenbolone will be done under the EU Additional Residue Testing Program.

XII. PORK FOR THE EUROPEAN UNION (PFEU) PROGRAM

All pork exported to the EU must originate from animals that have never been treated with hormonal growth promotants. In order for FSIS to provide export certification for this product, there must be assurances that there are effective controls in all phases of production in growing the animal, as well as at the slaughter establishment. FSIS has developed guidelines for the industry, which provide the system requirements and components of the program (Program for Certifying Pork Intended for Export to the EU). Though each phase of production (or ownership stage) will have to demonstrate that their system controls are adequate, emphasis will be placed on the controls at the finishing unit to ensure ractopamine hydrochloride (ractopamine) is not fed. The documented system will be audited by AMS (or by an AMS-accredited independent third party). AMS has developed instructions providing general policies and procedures for providing services under the PFEU Program MGC Instruction 710, Pork to the European Union Program Contact the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 for a fax copy of these documents.

A. Pork production

1. Pork production systems finishing hogs for the production of meat intended for export to the EU must receive third party verification through delivery to the slaughter establishment.

2. Each lot of hogs presented to the slaughter establishment must be accompanied by a signed producer affidavit certifying that the animals have never been fed ractopamine. (Example of Pork Producer

Affidavit) This affidavit can be transmitted electronically or by facsimile, but must be available when the shipment of hogs arrives at the establishment.

3. All hogs must be slaughtered and processed in a federally inspected establishment approved for production of products destined for the EU.

4. Each establishment must have a written program and procedures in place that will assure the production and shipment of product derived from animals that have never been administered hormonal growth promotants. AMS (or an AMS accredited independent third party) will review the program documentation for receiving hogs into the pork slaughter operations to ensure adequacy and continuity of animal identification procedures from the producer to the slaughter facility. Contact AMS, LSP for additional information regarding this program and to schedule the initial compliance review, which will be coordinated with the FSIS Export Coordination Staff, TSC. FSIS in-plant inspection personnel will ensure adequacy of the controls through the slaughter and processing establishment and will maintain operational oversight in the establishment.

B. In-process Controls

Each establishment involved in the production of pork must maintain documentation in accordance with an approved written control program and follow procedures that will assure the production and shipment of product derived from hogs that have not been fed ractopamine. Mandatory in-plant controls include:

1. Plant management must maintain documents to record the number of animals presented for slaughter and the number of animals slaughtered under EU mode of production.

1. Product destined for the EU must be appropriately identified and segregated throughout production according to the establishment's written control program.
2. Slaughter establishments must issue an affidavit confirming the eligibility of the pork for export to the EU, if carcasses are transferred to a separate cutting plant without an EU Health Mark applied in a tamper evident fashion (Example of Transfer Affidavit). Adequate records supporting control of product transferred to separate processing facilities and cold storage warehouses must be maintained by plant management.

C. FSIS Inspector-in-Charge Responsibilities (Pork IIC Procedures)

The IIC will verify that the establishment's written control program to determine if it is adequate to maintain product and identification controls throughout the slaughter, fabrication, processing, packaging process, to the point that the EU Health Mark is applied in a tamper evident fashion. FSIS inspection personnel will perform random checks of these procedures in operation throughout the EU production, as well as checks of the records maintained by plant management. In addition, FSIS will check company records, when necessary, to verify proper transfer for subsequent storage prior to certification of the product to the EU. Compliance oversight by FSIS includes:

1. Familiarity with the establishment's written control program.

2. Verification that the PFEU lot comes from an AMS approved premise. The affidavit will be reviewed to confirm that it complies with the parameters outlined in the establishment's written control program, including lot identification and authorized affidavit signer controls. The affidavit can be transmitted electronically or by facsimile but must be available for the verification check at the time the shipment of

hogs arrives at the slaughter establishment. Hogs arriving at the slaughter establishment without adequate identification or certification (producer affidavit) will not be permitted to be slaughtered for the EU until the deficiency is corrected according to the company's control procedures.

3. Performing additional random procedures to determine compliance with the program. Procedures will include all aspects from receiving through shipping and may include observation, review of records, or both. All records from an entire lot of product will be reviewed on a periodic basis. Reviewed records will be signed and dated.

4. If there is noncompliance with EU requirements or with the establishment's control program, the IIC will notify management and request correction of the deficiency. If a deficiency is not corrected, the IIC will withhold the EU health mark label (or brand). The labels (or brand) will be returned to the IIC and secured until correction is made. The IIC will document the noncompliance.

5. If repeated deficiencies occur, or a non-compliance is not corrected in a reasonable time period, the Export staff at the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 shall be notified through supervisory channels.

XIII. SOURCE OF RAW MATERIAL

Cutting and processing plants intending to prepare products for export to the EU must source the raw meat or poultry from EU approved slaughter establishments. The raw material must be eligible for export to the EU and bear the EU health mark. Adequate records supporting control of product transferred to separate processing facilities and cold storage warehouses must be maintained by plant management. Identification and segregation of the raw material must be acceptable to the IIC.

Raw material may be imported for the purpose of EU production provided it bears the EU Health Mark, as described above, and is eligible for importation into the United States. Imported product must be handled exclusively in facilities approved for the European Union, including import and cold storage facilities.

XIV. LABELING

A. Health Marks

1. Health mark labels must be applied to each carton of product in such a manner that the health mark label is destroyed when the package is opened. The health mark label must bear the following information:

a. an oval mark at least 2.5 in (6.5 cm) wide by 1.8 in (4.5 cm) high.

b. within the oval:

(1) in the center - the establishment number.

(2) in the upper or lower part - the letters USA.

(3) the letters must be at least 0.3 in (0.8 cm) high and the numbers should be at least 0.4 in (1 cm) high.

c. a sequential serial number that is unique to each health mark label for that establishment.

2. Health Mark for Wild Game

The health mark for wild game must be pentagonal shaped rather than oval. The pentagonal mark should be similar in size and bear the same information as the oval mark as indicated above. For information concerning the marking of small wild game, contact the export staff at the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990.

3. The health mark labels and brands must be kept under security by the IIC in a manner analogous to USDA brands. The IIC is responsible for maintaining an inventory of the health mark labels. Health mark labels should be given to plant management only while eligible products are being identified and marked and only for the length of time necessary to complete the task.

4. Meat carcasses must be stamped with ink or hot branded using a stamp or brand with the specifications described in A.1. and A.2. Those carcasses weighing more than 143 pounds (65 kg) must be stamped in at least the following places: external surface of the thighs, loins, back, brisket, and shoulder. Other carcasses must be marked in at least four places: on the shoulders and on the external surface of the thighs. Carcass stamping is not required if the carcasses are slaughtered, cut and packaged within the same establishment. Plant management must assure, to the satisfaction of the IIC, that proper identification of eligible carcasses is maintained throughout the establishment.

B. Beef Labeling - Additional labeling information must be present on beef arriving in the EU as of January 1, 2001. The labeling requirement applies to all beef intended for human consumption, with the exception of processed products and offals. The beef must be labeled in one of two ways:

1. Under "Option 1" exporters must display the following information on cartons and vacuum bags:

a. A reference number that links the meat with the individual animal and the farm, feedlot or ranch from which it originates. In the case of meat derived from a group of animals with a homogeneous background from the same premise, the reference number can link the meat with the group of animals rather than an individual animal. For the purposes of this labeling requirement, the size of a group of animals is limited to one day's production. There is no specific requirement for the format of the reference number as long as it provides linkage to the animal or group of animals and the origin premises.

b. The phrase "Slaughtered in the United States: Establishment (FSIS slaughter establishment number).

c. The phrase "Cut in the United States: Establishment (FSIS cutting establishment number).

d. The phrase "Origin: United States" if the animals were born, raised and slaughtered in the United States. In the case of imported animals, the countries of birth and of feeding must be indicated. If the animals were in a country other than the United States for less than 30 days, an indication of the other country is not required. (EU implementation of point 4 is January 1, 2002, rather than January 1, 2001.)

Note: Minced meat should indicate: "Prepared in the United States".

2. Under "Option 2" exporters must display the following information on cartons and vacuum bags:

a. "Non EC and slaughtered in the United States".

3. The labeling is mandatory to the retail level in the EU, or to the point of preparation in the case of product used for HRI purposes.

XV. FINLAND AND SWEDEN

Finland and Sweden require additional microbiological testing of fresh veal, beef, pork, and poultrymeat for salmonella prior to export certification. The sampling methods and number of samples to be taken varies with the class of product and the size of the consignment. Specific information regarding sampling methods, number of samples to be taken, and the testing methodology is available from the Export staff of the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990.

The additional testing is not required if the fresh veal, beef, pork or poultrymeat is destined for the manufacture of meat products in Sweden or Finland.

XVI. COMPLIANCE OVERSIGHT BY FSIS

Production modes

Plants must be in an EU production mode whenever producing for EU export. It is not necessary that establishments be in an EU mode when producing for non-EU markets. However, all establishments must provide an EU mode control program to the IIC to assure that all EU requirements are met before beginning EU production. The plant must be in the EU mode during prescreening by FSIS and during any EU review. The key role in assuring compliance with the requirements for export to the EU is with the IIC. If an approved plant is not in compliance with the EU requirements, the IIC should withhold the use of the EU health mark label (See Section XIII.) and notify plant management of the non-compliance. The EU health mark label should be returned to the secured location until the deficiency has been corrected. Product not bearing the EU health mark label was not produced according to the requirements for export to the EU and is not eligible for export certification to an EU member state.

XVII. DOCUMENTATION - LIST OF REQUIRED CERTIFICATES

A. These requirements describe the conditions for export to the EU as indicated in Council Decision 98/258 (the "Veterinary Equivalence Agreement). Issuance of the indicated certificates meats that the product complies with Decision 98/258. Only meat and poultry and meat and poultry products slaughtered, processed, and stored at approved establishments that meet the requirements described herein may be certified for export to the EU. All certificates for EU except FSIS Form 9060-5 must have a preprinted blue seal. All EU documents must be signed by an FSIS Veterinarian in a color other than black.

B. The following SRM statement must be typed in the remarks section or on a separate letterhead certificate for all meat from ruminants and products containing meat from ruminants:

"The product of animal origin does not contain, and is not derived from: specified risk material as defined in Annex

XI, section A, to regulation (EC) No 999/2001, produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals, produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

Carcasses, half carcasses and quarter carcasses may contain vertebal column on import."

Note: The following tissues are designated as specified risk material according to Annex XI 1. (a) of EC No. 999/2000

- the skull including the brain and eyes, the tonsils, the vertebral column excluding the vertebrae of the tail and the transverse processes of the lumbar vertebrae, but including dorsal root ganglia and spinal cord of bovine animals aged over 12 months, and the intestines from the duodenum to the rectum of bovine animals of all ages;
- the skull including the brain and eyes, the tonsils and the spinal cord of ovine and caprine animals aged over12 months or which have a permanent incisor erupted through the gum, and the spleen of ovine and caprine animals of all ages.

Although the injection of air during stunning is not permitted, captive bolt stunning alone is permitted.

C. Fresh meat

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-2 Public Health Certificate

FSIS Form 9180-1 Animal Health Certificate

FSIS Form 9180-3 Certificate of Authenticity for high quality beef or veal, if requested

Effective May 1, 2001, product certified by FSIS Form 9180-3 must be either graded USDA Prime or Choice or be produced under an AMS approved program which verifies that production practices meet the definition of "High-Quality beef" (see reverse side of form). Further information about establishing a program can be obtained from AMS Meat Grading and Certification Branch at (202) 720-1113.

In addition to the above certificates the following statement must be included in the "Remarks" section of FSIS Form 9060-5, Export Certificate of Wholesomeness, for fresh/frozen beef, pork, beef offal, and pork offal:

"The Meat is derived from animals which have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EEC".

D. Horsemeat

FSIS Form 9060-10 Horsemeat Export Certificate

FSIS Form 9180-2 Public Health Certificate

FSIS Form 9180-1 Animal Health Certificate and either:

1. FSIS Form 9205-1 Certificate Relative to a Test of Trichinae in Horsemeat, or

2. FSIS Form 9205-2 Certificate Relative to the Cold Treatment of Horsemeat.

E. Fresh poultry

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-8 Public Health Certificate for Fresh Poultry Meat

FSIS Form 9180-6 Animal Health Certificate for Fresh Poultry Meat for Human Consumption

F. Meat Preparations (including poultrymeat preparations)

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-10 Public Health Certificate for Meat Preparations

1. For red meat preparations, FSIS Form 9180-1 Animal Health Certificate

2. For poultrymeat preparations, FSIS Form 9180-6 Animal Health Certificate for Fresh Poultry Meat for Human Consumption

G. Meat Products (from red meat)

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS Form 9180-13 Public Health Certificate for Meat Products Intended for Export to the European Community

FSIS Form 9180-11 (English) or 9180-12 (English/German) Animal Health Certificate for Meat Products Intended for Consignment to the European Community

H. Meat Products (from poultrymeat and game meat)

FSIS Form 9060-5 Export Certificate of Wholesomeness

FSIS 9180-9 Public Health Certificate for Meat Products Obtained from Poultry Meat, Farmed Game Meat, Wild Game Meat and Rabbit Meat

FSIS Form 9180-11 (English) or 9180-12 (English/German) Animal Health Certificate for Meat Products Intended for Consignment to the European Community

I. Other products of animal origin - Member state certification should be issued pending determination of EU certification requirements.

J. Fresh meat of ratites -

FSIS 9060-5 Export Certificate of Wholesomeness

FSIS letterhead certification obtained from the TSC

K. Fresh meat of wild boar

FSIS Form 9060-5 Export certificate of Wholesomeness

FSIS letterhead certification obtained from the TSC

L. Animal casings

1. Depending upon the source of the casings, obtain one of the following certificates:

a. FSIS Form 9060-7, Animal Casings Export Certificate for Countries Requiring Ante-Mortem, Post-Mortem, and Fit for Human Food Statements (for casings derived from animals slaughtered in the U.S., or

b. FSIS Form 9060-17 , Animal Casing Export Certificate for Countries Requiring Ante-Mortem, Post-Mortem, and Fit for Human Food Statements (for casings derived form animals slaughtered in the U.S. and processed in Mexico), or

c. FSIS Form 9060-18, Animal Casings Export Certificate for Countries Requiring Ante-Mortem, Post-Mortem, and Sound and Clean Statements (for casings imported into the U.S.).

2. The following statement must be included in the "Remarks" section of the health certificate or on an accompanying FSIS letterhead certificate:

"The casings have been produced in accordance with the conditions laid down in Annex C, Chapter III of Directive 77\99\EEC."

3. FSIS Form 9180-7 Animal Health Certificate for Animal Casings Intended for Dispatch to the European Union. Note: The serial number from the health certificate used above must be placed in the block labeled "Reference Number of the Health Certificate " on FSIS Form 9180-7.

XVIII. OTHER REQUIREMENTS

A. Product for personal consumption - Products for personal consumption must meet all export requirements found in this document, i.e. be certified from an eligible plant (see EU plants lists) and be accompanied by all required certificates issued by an FSIS veterinarian. Hand carried or mailed items will not be allowed unless they meet these requirements. EU member countries are listed at the beginning of this document).

B. European Union requires treatment of all packing material made of conifer materials as a preventive measure against pinewood parasites. This includes wood pallets. USDA, APHIS has established a marking procedure for treated pallets. More information is available at the following web site:

http://www.aphis.usda.gov/ppq/swp/eunmwp.html

XVIV. PLANT APPROVAL PROCESS

A. Under Council Decision 98/258/EC (the Veterinary Equivalence Agreement):

1. The Export Staff of the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 will provide technical assistance regarding the provisions of the agreement to plant management and FSIS personnel. In addition, U.S. Meat Export Federation (303-623-6328) and U.S.A. Poultry and Egg Export Council (770-413-0006) may provide technical assistance to plant management interested in EU approval.

2. Plant management seeking EU approval should complete and submit FSIS 9080-3, Establishment Application for Export, to the Export Staff of the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 through FSIS supervisory channels. The Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990 may perform on-site visits to confirm that an establishment complies with the conditions of the new agreement.

3. Plants that comply with the conditions stated herein will be submitted to the EU for approval. FSIS will certify to the EU that U.S. meat and poultry establishments comply with the appropriate conditions as outlined above. The EU will approve and list the plants in a timely manner. Plants may begin producing for export to the EU under the conditions of the new agreement on the date of EU listing.

4. Farmed Game plants are reviewed by FSIS and determined to meet EU requirements for export. Farmed game plants are recommended to EU through FDA, as the "competent authority." Application and review matters are conducted by FSIS, Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990. For further information on FDA regulations covering farmed game, contact Marilyn Balmer at (202) 205-4400.

5. The EU has the right to audit approved plants to confirm that they comply with the conditions of the agreement.

B. Partial approvals - Applies to red meat only

Establishment management seeking approval of only the part of their plant that processes product for EU export can request partial plant approval for certain products under the following conditions:

1. The establishment shall develop a Quality Assurance (QA) program which addresses the mode of operation, the identification of product, and the segregation of the product from receiving to shipping.

Establishments which want to apply for partial approval must meet the facility requirements in the approved areas to ensure physical and/or time separation of approved and non-approved products.

2. The QA program shall include an establishment monitoring schedule and a log to document both monitoring actions and corrective actions.

3. The QA program shall be acceptable to the IIC and be available and acceptable to the EU auditor.

4. The IIC shall monitor the establishment's application of the QA program and document such monitoring and ensure correction of deficiencies.

5. The establishment must be able to demonstrate the program during an audit. All relevant documentation must be available.

C. Animal casing plants - Casing operations must be FSIS inspected. Plants not already under FSIS inspection for other products must apply for a grant of inspection, be approved for voluntary inspection, then apply for EU approval by submitting FSIS Form 9080-3 to the Export Staff at the Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990. In addition to meeting FSIS requirements, these plants must comply with special EU requirements such as medical certification, water testing, facility requirements such as the color of walls, the use of wood pallets as well as the specifications for the EU Health Mark described previously in this document. Casing plants are recommended to EU through FDA, as the "competent authority." Application and review matters are conducted by FSIS Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990.

XX. LISTS OF ELIGIBLE PLANTS

Lists of eligible plants for the various product categories are available through the Export Library. Plants must meet all EU requirements in addition to being listed on the appropriate list. Contact the FSIS Office of International Affairs, Washington, DC, Phone (202) 720-7990 , Fax (202) 720-7990.

Questions and Answers for the European Union Requirements

EUREQ16 5/1/2003